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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/583,066	05/30/2000	Erich Wanker	GPCG-P01-122	1672

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ROPES & GRAY LLP  
ONE INTERNATIONAL PLACE  
BOSTON, MA 02110-2624

EXAMINER
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MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/583,066

Applicant(s)

WANKER ET AL.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4-59, 63-66, 68-82 and 84-88 is/are pending in the application.
- ~~5) ☐ Claim(s) 3, 60-62, 67, and 83 have been canceled. Same withdrawn from consideration.~~
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-59, 63-66, 68-82 and 84-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 29 & 30.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### **DETAILED ACTION**

Upon reconsideration, applicants are hereby informed that the previous rejections in previous office actions were overcome, in a timely manner, as of the amendment, filed 1/29/03, thus fully satisfying applicants' response requirements to the final office action, mailed 9/30/02, on 1/29/03. All rejections set forth below have resulted from further reconsideration of the instant application. Also, due to the newly applied rejections hereinbelow summarized the finality of the office action, mailed 9/30/02, is withdrawn.

Applicants' arguments, filed 1/29/03, have been fully considered and they are deemed to be persuasive to overcome the previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

### **VAGUENESS AND INDEFINITENESS**

Claims 1, 2, 4-59, 63-66, 68-82, and 84-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 1 provides at least one set of host cells containing at least one genetic element which is defined in part (A) to also contain a selectable marker. This selectable marker is utilized for selection in step (B) via the phrase therein set forth as "said selectable marker" but without clear antecedent basis that the host cells in part (B) are those provided in step (A). Only the selectable marker from part (A) as noted above

Art Unit: 1631

is required in the part (B) practice of claim 1. Then, in step (C) of claim 1 the combining of host cells is cited with "at least two genetic elements" but without requiring such genetic elements as being those provided in host cells in step (A). These "at least two genetic elements" may be added elements over any already in the host cells of step (A). Said step (C) does cite the practice of the selecting step "as specified in (B)" but, as noted above, step (B) only requires the selectable marker of (A) but not the genetic element(s) of part (A). Also the selecting step in step (C) apparently utilizes the step (B) selectable marker but again does not indicate whether said step (B) marker is one of the "at least two genetic elements" cited in step (C) or not. Step (D) then permits interaction to occur, if any, but without this interaction being related specifically to the "potentially interacting molecules" of part (A) thus resulting in antecedent basis unclarity as to whether the interaction of step (D) is related to the "potentially interacting molecules" of part (A) or not. Similarly, the steps in instant claim 2 also contain these issues of a lack of clear antecedent bases for host cell content. Claims dependent directly or indirectly from either of claims 1 or 2 also contain these unclarity due to their dependencies. Clarification is requested via clearer claim wording.

The antecedent basis of what host cells are meant is also unclear in kit claim 84 in that there is no specific requirement that links parts (i) and (ii) within part (B) of claim 84. Claim 85 also contains this unclarity as being dependent from claim 84. Clarification via clearer claim wording is requested.

Claim 63 contains steps (N) and (O) but is an independent claim which suggests that there are earlier lettered steps (A) – (M) which confusingly are not recited, or, also

Art Unit: 1631

confusingly, may be meant to correspond to steps (A) – (M) which are present in claims 1 etc. Clarification is requested via clearer claim wording. Claim 64 also contains this unclarity due to depending from claim 63.

Claim 65, lines 1 and 2, cite the kit as being directed to “performing a method for the identification of at least one member of a pair or complex of interacting molecules”. It is noted that part (B) of claim 65 cites a DNA binding domain as well as an activation domain but lacks a clear and concise description of a “pair or complex of interacting molecules” as cited in said lines 1 and 2 of claim 65. The claim is therefore vague and indefinite as to whether the practice of lines 1 and 2 of claim 65 define the metes and bounds of the claim or parts (A) – (C) because lines 1 and 2 require interacting molecule practice whereas parts (A) – (C) do not. This unclarity is also present in claim 66 due to its dependence from claim 65. Clarification via clearer claim wording is requested.

Claims 65 and 66 are vague and indefinite because in part (C) of claim 65 the modifiers “digital” and “image” in the phrase “digital image capture” may or may not also be modifiers of “storage”, “processing”, and “analysis” but that this is not clearly worded as to what specifically is meant regarding the optional usage of these modifiers in claim 65. Clarification via clearer claim wording is requested.

In claim 1, lines 6-7, the phrase “genetic information encoding one or more potentially interacting molecules” is set forth. It is unclear how “information” even “genetic information” can encode such molecules. One interpretation is that information is not readable by a polymerase nor by ribosomes wherein a protein is made via

Art Unit: 1631

translation of mRNA. Encoding a protein which may be a potentially interacting molecule as in the claim practice is known to be a characteristic of DNA and/or RNA but not "information". This unclarity is also present in independent claims 2, 63, 65, and 84. Clarification via clearer claim wording is requested. Claims dependent directly or indirectly from any of claims 1, 2, 63, 65, or 84 also contain these unclaritys due to their dependencies. Clarification is requested via clearer claim wording.

The instant invention is apparently directed to methods and kits for the detection of interacting molecules. The invention is therefore reasonably interpreted as being directed to such detection utilizing host cells with a readout system which is not capable of being auto-activated. Auto-activation is defined in the instant specification on page 24, last full paragraph, as being a readout system activation via certain molecules without the need for interacting molecules as are desired to be specifically detected. The kit claims 84 and 85 are directed to detecting host cells wherein the expression of auto-activating versus non-auto-activating molecules in part (B)(ii) is differentiated. This kit is therefore reasonably interpreted as not being commensurate with the practice of the invention as set forth in the specification because it appears to be directed to evaluating the auto-activation potential of a molecule which is not the goal of the instant invention. For example, instant claim 1, part (B), cites the utilization of a medium which "precludes" growth of host cells upon auto-activation which removes auto-activation as an option or even concern for any the therein cited host cells. The instant invention apparently is directed to the detection of interacting molecules and not auto-activating molecules. Clarification via clearer claim wording is requested.

Art Unit: 1631

Abbreviations in claims are vague and indefinite as to what is meant unless either replaced by the full name or accompanied by the full name, usually in parentheses. Abbreviations are set forth in various instant claims, such as the genes cited in claim 8, for example. Clarification via clearer claim wording is requested.

### **PRIOR ART**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 65 and 66 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Fields et al. (P/N 5,283,173):

Fields et al. discloses the preparation of a kit with vectors and host cells in column 5, line 28, through column 6, line 68. A DNA binding domain with an activation domain is described as being present in the vectors with marker genes for a readout of a signal if interaction of test proteins has occurred, thus anticipating such a readout system. A readout system which clearly cites color indication is set forth in column 6, lines 60-62, which anticipates the visual means as required in instant claim 65 wherein analysis of the color result is concluded as being a measure of GAL4 function. Part (C) of instant claim 65 in the last two lines ends with the phrase "and/or analysis" as a

Art Unit: 1631

characteristic of the "visual means" in the second line of part (C). The "and/or" wording in said phrase is reasonably interpreted as indicating that solely "analysis" is a possible characterization of what the visual means includes in the last 2 lines of said part (C) of claim 65. The host cells of instant claim 66 are described as clearly set forth options in column 8, lines 49-51.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fields et al. (P/N 5,283,173); taken in view of Augenlicht (P/N 4,981,783).

.Fields et al. describes the preparation of a kit with vectors and host cells in column 5, line 28, through column 6, line 68. A DNA binding domain with an activation domain is described as being present in the vectors with marker genes for a readout of a signal if interaction of test proteins has occurred. A readout system is described as utilizing color colony detection on appropriate media as set forth in column 6, lines 60-62. Fields et al., however lacks digital visual means for image capture, storage,



Art Unit: 1631

processing and analysis as in part (C) of instant claim 65. It is noted that this rejection is directed to claim embodiments other than the "analysis" only visual means of part (C) of instant claim 65 based rejection under 35 U.S.C. 102 as summarized above.

Augenlicht summarizes the digitization of data from cloning experiments in the abstract. The BACKGROUND OF THE INVENTION section in columns 1-4 of Augenlicht also summarizes the screening of colonies for a variety of general Biotechnology studies wherein gene expression is analyzed as the subject matter of the invention therein disclosed. See, specifically, column 3, line 55, through column 4, line 2, wherein a computer database is described as storing data for the processing and analysis of expression screening methods. Motivation to perform such computer data processing etc. is set forth in column 3, line 56, through column 4, line 2, wherein a large number of sequences may be analyzed as well as the detection of complex patterns of gene expression as is commonly cited as occurring. Digitization of such expression experimental data is specifically described as exemplified in column 7, line 48, through column 8, line 13. Column 8, line 14, et seq. describes storage, processing, and analysis of the data of this type.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform the Fields et al. expression screening assay with digital visualization etc. such as set forth in Augenlicht because the improvements in Augenlicht for generic expression screening assays as in Fields et al. are motivated and suggested for improved large number assay experiments to analyze complex patterns as is commonly present in such screening procedures. The host cells of instant claim 66

Art Unit: 1631

are described as clearly set forth options in column 8, lines 49-51, and thus clearly suggested and motivated within the Fields et al. invention practice.

### **CUMULATIVE CITATIONS**

Arkin et al. (1990) and Yang et al. (1988) are listed on the attached PTO Form 892 as being cumulative references regarding digital image processing of for screening methods wherein bacterial expression is being studied, but not deemed needed for the above rejections.

No claim is allowed.

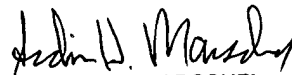
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 12, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER